

1 CLAUDIA M. VETESI (CA SBN 233485)  
CVetesi@mofo.com  
2 Lena Gankin (CA SBN 333047)  
LGankin@mofo.com  
3 MORRISON & FOERSTER LLP  
425 Market Street  
4 San Francisco, California 94105-2482  
Telephone: 415.268.7000  
5 Facsimile: 415.268.7522

6 NICOLE V. OZERAN (CASBN 302321)  
NOzeran@mofo.com  
7 MORRISON & FOERSTER LLP  
707 Wilshire Boulevard  
8 Los Angeles, California 90017-3543  
Telephone: 213.892.5200  
9 Facsimile: 213.892.5454

10 Attorneys for Defendant  
NATURE'S PATH FOODS, INC.

11  
12 UNITED STATES DISTRICT COURT  
13 NORTHERN DISTRICT OF CALIFORNIA  
14

15 MOLLY BROWN, PARSA MILLER, and  
16 LAUREN MORGAN as individuals, on behalf of  
themselves, the general public and others similarly  
situated,

17 Plaintiff,

18 v.

19 NATURE'S PATH FOODS, INC.,

20 Defendant.  
21

Case No. 4:21-cv-05132-HSG

**DEFENDANT NATURE'S PATH  
FOODS, INC.'S SUPPLEMENTAL  
BRIEFING PURSUANT TO THE  
COURT'S JANUARY 27, 2022  
ORDER (ECF NO. 41)**

## I. INTRODUCTION

Plaintiffs allege that Nature's Path misrepresents the amount of protein on the labels of more than 50 products, including cereals, granola, oatmeal and waffles ("Products"). (ECF No. 1, ¶¶ 3, 48.) Specifically, Plaintiffs contend that the protein amounts on the front labels of *all* of the Products are overstated because: (1) Plaintiffs purportedly conducted "amino acid content testing"<sup>1</sup> on just one Nature's Path product, the Hemp Hearts Granola, which revealed that the product had 57% less protein (quantity) than stated on its front label; and (2) when Plaintiffs adjusted the Hemp Hearts Granola's amino acid content for protein digestibility (quality) based on their "test" results using FDA's "Protein Digestibility Corrected Amino Acid" score ("PDCAAS"),<sup>2</sup> the product contained even less protein. (ECF No. 1, ¶ 5.)

Plaintiffs' front-label<sup>3</sup> theories are premised on a misunderstanding of the relevant FDA regulations. Nature's Path moved to dismiss Plaintiffs' complaint (ECF No. 18), arguing that Plaintiffs' claims are preempted, implausible, and insufficiently pled, because FDA regulations do not require Nature's Path to use Plaintiffs' seemingly made-up "amino acid content test" or adjust the amount of protein for protein quality using PDCAAS when making *front-label* claims. (ECF No. 18, at 7-8.) Instead, FDA regulations permit that the total amount of protein may be calculated using another FDA-approved database or the "nitrogen method," as specified in 21

---

<sup>1</sup> Plaintiffs provide little information regarding their purported "amino acid content test"—no methodology, no specific test results, no citations to amino acid content testing in the federal regulations, and no specific standards against which to compare the test results.

<sup>2</sup> PDCAAS is a method used to score the "quality" of protein based on how it is digested by the body. *See* Food Labeling: Mandatory Status of Nutrition Labeling and Nutrient Content Revision, Format for Nutrition Label, 58 Fed. Reg. 2079, 2103 (Jan. 6, 1993). PDCAAS is not a test conducted on the food, but a calculation comparing the amino acids in the food to a scoring pattern. For example, the highest PDCAAS value of a food is 1.0, indicating that the protein will provide 100% (or more) of all the amino acids required in the diet. *See* ECF No. 18, at 6.

<sup>3</sup> In addition to these front-label claims, Plaintiffs allege that Nature's Path failed to include a "percent daily value" of protein on the back nutrition facts panel. (ECF No. 1, ¶ 6.) As Nature's Path explained in its Motion to Dismiss, that claim is impliedly preempted under *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341, 353 (2001) because Plaintiffs seek to privately enforce the FDCA (ECF No. 18, at 10), and does not support a claim of deception where Plaintiffs do not allege that they read or relied on the back label. (ECF No. 18, at 10-11; 16.) But because FDA's newly-issued guidance (ECF No. 40, Ex. A ) does not impact the analysis of Plaintiffs' back-label claim, Nature's Path does not discuss it further in this supplemental brief.

1 C.F.R. § 101.9(c)(7) (“Protein content may be calculated on the basis of the factor 6.25 times the  
2 nitrogen content of the food...”). And federal regulations only require food manufacturers to  
3 adjust for protein digestibility using PDCAAS for the daily value percentage on the **back** label.  
4 21 C.F.R. § 101.9(c)(7)(ii). As such, Plaintiffs’ claims are an impermissible attempt to impose  
5 requirements different from federal regulations. Moreover, any claim of deception is implausible  
6 because Plaintiffs cannot demonstrate that consumers were misled by Nature’s Path’s truthful and  
7 accurate labeling based solely on Plaintiffs’ purported “amino acid” test of one product.

8 Plaintiffs push back, arguing that because 21 CFR § 101.13(i)(3) requires that Nature’s  
9 Path “avoid stating a misleading amount of protein,” “the only reasonable interpretation of  
10 § 101.13(i)(3) is that it requires manufacturers to use the PDCAAS method to make front label  
11 protein claims.” (ECF No. 23, at 8.) Moreover, Plaintiffs rely on Judge Seeborg’s now-uncertain<sup>4</sup>  
12 decision in *Minor v. Baker Mills, Inc.*, No. 3:20-cv-02901-RS (N.D. Cal.) for the proposition that  
13 a front-label protein content claim “must calculate those grams using the amino acid method.”  
14 (*Id.*) Plaintiffs are incorrect.

15 On January 11, 2022, after Nature’s Path’s Motion to Dismiss was fully-briefed, FDA  
16 issued guidance under the heading “Industry Resources on the Changes to the Nutrition Facts  
17 Label,” confirming Nature’s Path’s positions. (ECF. No. 40, Ex. A.)<sup>5</sup> FDA considered the  
18 following question: “There are separate methods for determining the number of grams of protein  
19 in a serving for declaration on the Nutrition Facts label and for determining the percent Daily  
20 Value of protein for the Nutrition Facts label (21 CFR 101.9(c)(7)). Which method should be  
21 used when calculating protein values for use in protein nutrient content claims?” (*Id.*, at 12.)  
22 FDA’s response was unambiguous:

---

23  
24 <sup>4</sup> As discussed in Nature’s Path’s Reply in Support of its Motion to Dismiss (ECF 26, at 1-  
25 2), Judge Seeborg is reconsidering his decision in *Minor v. Baker Mills, Inc.*, No. 3:20-cv-02901-  
26 RS (N.D. Cal.): “[I]t appears *Minor*’s finding that there was no preemption may rest on a  
mistaken understanding that the language in 21 C.F.R. § 101.9(c)(7)(ii) endorsed use of the amino  
acid method, as opposed merely to calling for application of PDCAAS.” *Chong v. KIND LLC*,  
No. 21-cv-04528-RS, 2021 U.S. Dist. LEXIS 182395, at \*4 (N.D. Cal. Sept. 23, 2021).

27 <sup>5</sup> Nature’s Path sought leave to file a Notice of Supplemental Authority concerning FDA’s  
28 guidance (ECF No. 38), which the Court granted. (ECF No. 41.)

1 “By design, 21 CFR 101.9(c)(7) specifically provides for two  
2 different methods for determining protein values. The regulation  
3 states, in 21 CFR 101.9(c)(7), that protein content may be  
4 calculated on the basis of the factor 6.25 times the nitrogen content  
5 of the food [the nitrogen method]... Additionally, 21 CFR  
6 101.9(c)(7)(ii) provides the method for determining protein content  
7 using the protein digestibility-corrected amino acid score for use in  
8 calculating the percent Daily Value [PDCAAS]. **Determination of  
9 compliance for protein nutrient content claims will be based on  
10 the use of the methods provided in 21 CFR 101.9(c)(7),  
11 including either of the methods mentioned above.**

12 (*Id.*, at 12-13 (emphasis added).)

13 FDA’s guidance regarding protein content confirms that Plaintiffs’ claims are (1)  
14 preempted, because Nature’s Path is permitted to use the nitrogen method, not Plaintiffs’  
15 preferred “amino acid content test” or PDCAAS to calculate front-label protein content; and (2)  
16 implausible, because Plaintiffs cannot allege that consumers were deceived by Nature’s Path’s  
17 lawful protein labeling. Plaintiffs’ claims should therefore be dismissed without leave to amend.

## 18 **II. PLAINTIFFS’ CLAIMS ARE PREEMPTED**

19 In its Motion to Dismiss, Nature’s Path explained that FDA regulations require that the  
20 amount of “total protein” per serving appear on the “Nutrition Facts” panel on a product label, as  
21 outlined in 21 C.F.R. § 101.9. (ECF No. 18, at 3.) A food manufacturer is allowed to also list  
22 information that appears in the “Nutrition Facts” elsewhere on the product, including on its front  
23 label. 21 C.F.R. § 101.13(b) & (c). Nature’s Path explained that federal regulations permit it to  
24 utilize the nitrogen method or another FDA-approved database, and do not require it to calculate  
25 protein content using an “amino acid content test” or adjust for digestibility using PDCAAS when  
26 making *front label* claims mirroring the claims made in the “Nutrition Facts” panel. (ECF No.  
27 18, at 6-8.) FDA’s newly-issued guidance supports Nature’s Path’s position.

28 In its guidance regarding protein nutrient content claims, FDA clarifies that its regulations  
do not state that a front label protein claim must be calculated using an “amino acid content test”  
or adjusted for digestibility via PDCAAS. Instead, FDA regulations provide that the total amount  
of protein *may* be calculated using the nitrogen method, and PDCAAS *must* be used for  
calculating percent daily value on the *back* nutrition panel only. (ECF No. No. 40, Ex. A, at 13  
 (“Additionally, 21 CFR 101.9(c)(7)(ii) provides the method for determining protein content using

1 [PDCAAS] for use in calculating *the percent Daily Value.*”) (emphasis added).) Plaintiffs may  
2 disagree with FDA’s regulatory scheme, but “state law cannot be used to fill what private litigants  
3 perceive to be gaps in the regulatory requirements imposed by federal law.” *Chi. Faucet Shoppe,*  
4 *Inc. v. Nestle Waters N. Am., Inc.*, 24 F. Supp. 3d 750, 759 (N.D. Ill. 2014).

5 Because Plaintiffs attempt to require Nature’s Path to calculate its front label protein  
6 claims using the amino acid method and/or PDCAAS, Plaintiffs seek to impose an obligation in  
7 addition to or different than those in FDA regulations. Such claims are preempted. *See e.g.,*  
8 *Greenberg v. Target Corp.*, 985 F.3d 650, 657 (9th Cir. 2021) (a requirement not identical to the  
9 federal regulations is preempted). And “[i]f a claim is preempted by federal law, it fails to state a  
10 claim upon which a relief can be granted under Rule 12(b)(6).” *Yumul v. Smart Balance, Inc.*,  
11 No. CV 10–00927 MMM (AJWx), 2011 WL 1045555, at \*5 (C.D. Cal. Mar. 14, 2011).

12 *Durnford v. Musclepharm Corp.*, No. 15-cv-00413-HSG, 2015 WL 9258079 (N.D. Cal.  
13 Dec. 18, 2015), *rev’d* on other grounds, 907 F.3d 595 (9th Cir. 2018) is instructive. There, in  
14 dismissing the plaintiff’s protein labeling claims, this Court held that “Plaintiff seeks to hold  
15 Defendant liable for calculating protein content using a method prescribed by FDA regulations, in  
16 violation of the FDCA’s express preemption provision.” *Durnford*, 2015 WL 9258079, at \*3-5.  
17 Other courts have agreed and similarly dismissed cases where plaintiffs seek to impose protein  
18 labeling requirements additional to FDA’s requirements. *See e.g., Mee v. IA Nutrition, Inc.*, No.  
19 C–14–5006 MMC, 2015 WL 2251303, at \*3 (N.D. Cal. May 13, 2015) (claim challenging use of  
20 nitrogen method was preempted where “indeed, [it] is a challenge to the very method allowed by  
21 the FDA”); *Ulrich v. Probalance, Inc.*, No. 16 C 10488, 2017 WL 3581183, at \*4 (N.D. Ill. Aug.  
22 18, 2017) (“the FDCA and its implementing regulations do not strictly require pure protein  
23 content claims . . . to be calculated according to the PDCAAS method.”).

24 For these reasons, Plaintiffs’ claims are preempted and should be dismissed.

### 25 **III. PLAINTIFFS’ CLAIMS ARE IMPLAUSIBLE**

26 As Nature’s Path showed in its Motion to Dismiss, Plaintiffs’ allegations that reasonable  
27 consumers are likely to be deceived by front-label protein content claims is implausible, because  
28 (1) the labels list the accurate amount of protein pursuant to FDA regulations; and (2) reasonable

1 consumers are not aware of technical testing for protein, such as the nitrogen and “amino acid”  
2 methods, and such distinctions would not be material to their purchasing decisions. (ECF No. 18,  
3 at 13.) In response, Plaintiffs argue that Nature’s Path deceived consumers by failing to provide  
4 the stated amount of protein “from a human nutritional standpoint due to Nature’s Path’s use of  
5 poor *quality* proteins,” which they allege are not fully digestible by the human body. (ECF No.  
6 23, at 16 (emphasis added).) FDA’s newly-issued guidance, however, establishes the  
7 implausibility of Plaintiffs’ claims.

8 FDA’s guidance states that front label protein content claims may be calculated using the  
9 nitrogen method or another FDA-approved database. (ECF No. No. 40, Ex. A.) Plaintiffs do not  
10 and cannot allege that Nature’s Path did not calculate its products’ protein *quantity* using an  
11 approved method. Accordingly, any claim that Plaintiffs were misled by the true protein quantity  
12 representation is implausible. *See e.g., Stewart v. Kodiak Cakes, LLC*, 537 F. Supp. 3d 1103,  
13 1153 (S.D. Cal. 2021) (a reasonable person would not find that the use of “protein-packed” on a  
14 label to be misleading, where the label accurately stated the true protein content “clearly on the  
15 front of the box.”); *Otero v. Zeltiq Aesthetics, Inc.*, No. CV 17-3994-DMG (MRWx), 2018 WL  
16 3012942, at \*2 (C.D. Cal. June 11, 2018) (plaintiffs failed to explain “how that true  
17 representation—on its own—could cause reasonable consumers to erroneously” come to a  
18 conclusion). That Plaintiffs believe Nature’s Path’s protein sources to be of “poor *quality*,” does  
19 not change the fact that Plaintiffs could not have been misled by a truthful front label  
20 representation of protein *quantity*.

21 Nature’s Path accurately displays the protein quantity of its Products to consumers, and  
22 courts repeatedly dismiss consumer fraud claims where plaintiffs “allege[] that a consumer will  
23 read a true statement on a package and will then ... assume things about the products *other than*  
24 *what the statement actually says.*” *Red v. Kraft Foods, Inc.*, No. 10-1028-GW(AGRx), 2012 WL  
25 5504011, at \*3 (C.D. Cal. Oct. 25, 2012). The same should be found here.

#### 26 **IV. CONCLUSION**

27 Accordingly, Nature’s Path respectfully requests that this Court dismiss Plaintiffs’  
28 Complaint without leave to amend.

1 Dated: February 3, 2022

2 CLAUDIA VETESI  
3 MORRISON & FOERSTER LLP

4 By: Claudia Vetesi  
5 CLAUDIA VETESI

6 Attorneys for Defendant  
7 NATURE'S PATH FOODS, INC.  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28